

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA**

**IN RE: ACTOS PRODUCTS LIABILITY
LITIGATION**

MDL No. 6:11-md-2299

**BETTY J. BEAUBIEN, INDIVIDUALLY AND
ON BEHALF OF THE ESTATE OF
LOUIS BEAUBIEN, DECEASED**

JUDGE DOHERTY

Plaintiff,

MAGISTRATE JUDGE HANNA

v.

Civil Action No.: 6:14-cv-2413

TAKEDA PHARMACEUTICALS USA, Inc. (f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, Inc.), TAKEDA PHARMACEUTICALS AMERICA, Inc., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, Inc., TAKEDA CALIFORNIA, Inc. (f/k/a TAKEDA SAN DIEGO, Inc.), and TAKEDA PHARMACEUTICALS INTERNATIONAL, Inc., TAKEDA PHARMACEUTICAL CO. LTD., and ELI LILLY & COMPANY,

COMPLAINT

Defendants.

Plaintiff by her attorneys, Aylstock, Witkin, Kreis & Overholtz, PLLC, hereby brings this cause of action against Defendants TAKEDA PHARMACEUTICALS USA, Inc. (f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, Inc.), TAKEDA PHARMACEUTICALS AMERICA, Inc., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, Inc., TAKEDA CALIFORNIA, Inc. (f/k/a TAKEDA SAN DIEGO, Inc.), and TAKEDA PHARMACEUTICALS INTERNATIONAL, Inc., TAKEDA PHARMACEUTICAL CO. LTD, and ELI LILLY & COMPANY (“Lilly” or collectively with

Takeda as “Defendants”) and as for her Complaint alleges, upon information and belief and based on the investigation to date of counsel, as follows:

NATURE OF THE CASE

1. This is a personal injury/wrongful death action on behalf of plaintiff decedent and loss of consortium on behalf of Plaintiff and decedent’s heirs against Defendants who manufactured, sold and were responsible for the defective drug Actos (pioglitazone) and/or Actosplus Met, Actosplus Met XR, Duetact (hereinafter “Actos”). Actos is a diabetes medication used to improve blood sugar (glucose) control in adults such as plaintiffs with type II diabetes that caused plaintiff’s bladder cancer.

SUBJECT MATTER JURISDICTION AND VENUE GENERALLY

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as set forth below, Plaintiff is a citizen of states that are different from the states where the Defendants are incorporated and have their principal places of business.

3. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

4. Venue is proper within this District pursuant to 28 U.S.C. § 1391 because it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c).

PLAINTIFF SPECIFIC ALLEGATIONS

5. Plaintiff, Betty J. Beaubien, individually and on behalf of the Estate of Louis Beaubien, deceased, alleges as follows:

- a. Plaintiff, Betty J. Beaubien, is a natural person and a citizen and resident of Michigan.
- b. Plaintiff Betty J. Beaubien brings a survival action on behalf of the Estate of Louis Beaubien and brings a wrongful death action individually as the spouse of Louis Beaubien
- c. At the time of Decedent's death and all other relevant times, Decedent was a resident of Michigan.
- d. Decedent Louis Beaubien ingested the prescription drug Actos as prescribed and directed by his physician and was injured and suffered bladder cancer and death as a result of his use of Actos.
- e. Decedent died on March 30, 2012 in Lenawee County, Michigan.
- f. Plaintiff Betty J. Beaubien's loss of consortium claims are alleged in the seventh cause of action.

PARTY DEFENDANTS AND PERSONAL JURISDICTION

6. Upon information and belief, Defendant, TAKEDA PHARMACEUTICALS U.S.A. INC., (f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.) is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA PHARMACEUTICALS U.S.A. INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

7. Defendant, TAKEDA PHARMACEUTICAL CO. LTD, is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan. As part of its

business, TAKEDA PHARMACEUTICAL CO. LTD is involved in the research, development, sales, and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

8. Defendant, TAKEDA PHARMACEUTICALS LLC., is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA PHARMACEUTICALS LLC is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

9. Defendant, TAKEDA PHARMACEUTICALS INTERNATIONAL INC., is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. As part of its business TAKEDA PHARMACEUTICALS INTERNATIONAL INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

10. Defendant, TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC., is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. As part of its business TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

11. Defendant, TAKEDA CALIFORNIA INC., (f/k/a TAKEDA SAN DIEGO INC.) is a California corporation, having a principal place of business at 10410 Science Center Drive, San Diego, CA 92121. As part of its business TAKEDA CALIFORNIA INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

12. Defendant ELI LILLY AND COMPANY is an Indiana corporation, having a

principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. As part of its business ELI LILLY AND COMPANY is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

13. Upon information and belief, at relevant times, Defendants were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of Michigan, either directly or indirectly through third parties or related entities, its products, including Actos and pioglitazone hydrochloride.

14. At relevant times, Defendants conducted regular and sustained business and engaged in substantial commerce and business activity in the States of Michigan, which included but was not limited to selling, marketing and distributing its products including Actos and pioglitazone hydrochloride in Michigan.

15. Upon information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America including the States of Michigan and Defendants derived and derive substantial revenue from interstate commerce.

16. Upon information and belief, Defendant, TAKEDA PHARMACEUTICAL COMPANY LIMITED, is a company domiciled in Japan and is the parent/holding company of Defendants, TAKEDA PHARMACEUTICALS INTERNATIONAL INC., TAKEDA PHARMACEUTICALS U.S.A. INC., TAKEDA PHARMACEUTICALS LLC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC., and TAKEDA CALIFORNIA INC.

17. Upon information and belief, at all relevant times, Defendant, TAKEDA

PHARMACEUTICAL COMPANY LIMITED, exercised and exercises dominion and control over Defendants, TAKEDA PHARMACEUTICALS INTERNATIONAL INC., TAKEDA PHARMACEUTICALS U.S.A. INC., TAKEDA PHARMACEUTICALS LLC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC., and TAKEDA CALIFORNIA INC..

18. Upon information and belief, at all relevant times, Defendant, TAKEDA PHARMACEUTICAL COMPANY LIMITED, expected or should have expected that its acts would have consequences within the United States of America and the State of Michigan, and derived and derive substantial revenue from interstate commerce.

19. Upon information and belief, at all relevant times, Defendants, including Defendant, TAKEDA PHARMACEUTICAL COMPANY LIMITED, have transacted and conducted business in the State of Michigan and/or contracted to supply goods and services within the State of Michigan and this cause of action has arisen from same.

20. Upon information and belief, at all relevant times, Defendants, including Defendant, TAKEDA PHARMACEUTICAL COMPANY LIMITED, committed a tortious act within the State of Michigan causing injury within the State of Michigan out of which act(s) this cause of action arises.

21. Upon information and belief, at all relevant times, Defendants, including Defendant, TAKEDA PHARMACEUTICAL COMPANY LIMITED, committed tortious act(s) within the State of Michigan out of which act(s) this cause of action arises.

22. Upon information and belief, at all relevant times, Defendant ELI LILLY AND COMPANY expected or should have expected that its acts would have consequences within the

United States of America and the State of Michigan, and derived and derive substantial revenue from interstate commerce.

23. Upon information and belief, at all relevant times, Defendants, including Defendant ELI LILLY AND COMPANY have transacted and conducted business in the State of Michigan and/or contracted to supply goods and services within the State of Michigan and this cause of action has arisen from same.

24. Upon information and belief, at all relevant times, Defendants, including Defendant ELI LILLY AND COMPANY committed a tortious act within the State of Michigan causing injury within the State of Michigan out of which act(s) this cause of action arises.

FACTUAL BACKGROUND

25. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Actos and pioglitazone hydrochloride for treatment of Type 2 Diabetes Mellitus.

26. Actos received FDA approval in 1999 to treat Type 2 Diabetes Mellitus.

27. Actos was jointly launched by Takeda North America and Lilly in 1999.

28. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos, a partnership Takeda Limited described as “a great success” and “mutually beneficial to both companies.”

29. Prior to applying for and obtaining approval for Actos, Defendants knew or should have known that Actos use in humans was associated with and/or would cause the induction of bladder cancer and Defendants possessed pre-clinical scientific studies including animal

evidence, which evidence Defendants knew or should have known was a signal that bladder cancer risk needed to be further tested and studied before placing Actos on the market.

30. Despite bladder cancer findings in animal model carcinogenicity studies and other pre-clinical evidence, Defendants failed to adequately conduct complete and proper testing of Actos prior to filing its New Drug Application of Actos.

31. It is now known that additional bladder cancer evidence from human clinical trials also became known to Defendants in the early 2000's.

32. From the date of approval to market Actos, Defendants made, distributed, marketed and sold Actos without adequate warning to Plaintiff's prescribing physicians, or Plaintiff, that Actos was associated with and/or could cause bladder cancer and presented a risk of bladder cancer in patients who used it and without adequate warning that Defendants had not adequately conducted complete and proper testing and studies of Actos with regard to carcinogenicity.

33. For over 10 years and to date, Defendants concealed and failed to completely disclose its knowledge that Actos was associated with or could cause bladder cancer or its knowledge that it had failed to fully study and test regarding that risk.

34. Defendants' failure to disclose information that they possessed regarding the failure to adequately study and test Actos for bladder cancer risk further rendered warnings for this medication inadequate.

35. Upon information and belief, Defendants ignored the association between the use of Actos and pioglitazone hydrochloride and the risk of developing bladder cancer.

36. On June 7, 2011, the Caisse nationale de l'assurance maladie, at the request of the French regulatory agency, published a report concluding that there is a statistically significant

association between exposure to pioglitazone (Actos) and bladder cancer and that the risk increased with exposure longer than one year.

37. On June 9, 2011, the European Medicine Agency suspended the use of Actos in light of the French Marketing Authorization Committee and the French National Pharmacovigilance Committee's findings regarding the increased risk of bladder cancer.

38. On June 10, 2011, Germany's Federal Institute for Drugs and Medical Devices suspended the use of Actos.

39. On June 15, 2011, the FDA informed the public that use of the diabetes medication Actos for more than one year may be associated with an increased risk of bladder cancer. The Actos label was then changed to reflect this information in the Warnings and Precautions section as well as the patient Medication Guide to include information regarding the risk of bladder cancer.

40. FDA further recommended on June 15, 2011, that healthcare physicians discontinue pioglitazone use in patients with active bladder cancer.

41. On June 17, 2011, Health Canada Press Release indicated that in light of studies suggesting an increased risk of bladder cancer with the diabetes drug pioglitazone, as well as actions taken by other regulatory agencies, Health Canada informed healthcare professionals and Canadians that it is undertaking a review of the drug's status.

42. As a result of using Defendants' Actos, Plaintiff was caused to suffer bodily injury including cancerous tumor(s) in his bladder and was thus caused to sustain severe and permanent personal injuries, pain, suffering, mental anguish and death.

43. The injuries and damages sustained by Plaintiff were caused or substantially contributed to by Defendants' Actos and the Defendants' wrongful conduct.

44. The product warnings for Actos in effect during the time period Plaintiff used Actos were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians as well as Plaintiff of the bladder cancer risk associated with this drug.

45. Defendants did not provide adequate warnings to Plaintiff's doctors, Plaintiff, the health care community and the general public about the increased risk of serious adverse events that are described herein.

46. Had Plaintiff been adequately warned of the potential life-threatening side effects of Defendants' Actos, Plaintiff would not have purchased or taken Actos and would have chosen to request other treatments or prescription medications.

47. By reason of the foregoing, Plaintiff developed serious and dangerous side effects including bladder cancer and death, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

**EQUITABLE TOLLING OF APPLICABLE
STATUTES OF LIMITATIONS**

48. The running of any statute of limitation has been tolled by reason of Defendants' conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff Decedent and Plaintiff Decedent's prescribing physicians the true risks associated with Actos and pioglitazone hydrochloride.

49. As a result of Defendants' actions, Plaintiff Decedent and Plaintiff Decedent's prescribing physicians were unaware, and could not reasonably know or have learned through

reasonable diligence that Plaintiff Decedent had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

50. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of Actos and pioglitazone hydrochloride. Defendants were under a duty to disclose the true character, quality and nature of Actos because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Plaintiff Decedent, his medical providers and/or to his health facilities.

51. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff Decedent and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

FIRST CAUSE OF ACTION
AS AGAINST DEFENDANTS
(NEGLIGENCE)

52. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

53. Defendants had a duty to Plaintiff Decedent, Plaintiff and the general public to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Actos and pioglitazone hydrochloride into the stream of commerce, including a duty to assure that Actos and pioglitazone hydrochloride would not cause users to suffer unreasonable, dangerous side effects such as cancer.

54. Defendants failed to exercise ordinary care and/or were reckless in designing,

researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Actos into interstate commerce in that Defendants knew or should have known that using Actos caused a risk of unreasonable, dangerous side effects, including bladder cancer and death.

55. Despite the fact that Defendants knew or should have known that Actos was associated with and/or caused bladder cancer, Defendants continued to market, manufacture, distribute and/or sell Actos to consumers, including the Plaintiff.

56. Defendants knew or should have known that consumers such as the Plaintiff Decedent would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

57. Defendants' negligence and/or recklessness were the legal and proximate cause of Plaintiff Decedent's injuries, harm and economic loss which they suffered.

58. As a result Defendants' negligence and/or recklessness, Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which were permanent and lasting in nature, including metastatic cancer, physical pain and mental anguish, including diminished enjoyment of life, as well as surgical procedures, medical treatment, monitoring and/or medications, and finally, death.

59. As a result of the foregoing acts and omissions Plaintiff required health care and services and did incur medical, health, incidental and related expenses.

60. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SECOND CAUSE OF ACTION
AS AGAINST DEFENDANTS
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

61. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

62. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Actos into the stream of commerce, and in the course of same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff Decedent directly and Plaintiff Decedent's physician to warn of risks associated with the use of the product.

63. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of Actos and pioglitazone hydrochloride and/or are associated with the use of Actos and pioglitazone hydrochloride.

64. The Actos and pioglitazone hydrochloride manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after Defendants knew or should have known of the risks of bladder cancer from Actos use, they failed to provide adequate warnings to consumers of the product, including Plaintiff Decedent and Plaintiff Decedent's physicians, and continued to aggressively promote Actos.

65. Due to the inadequate warning regarding bladder cancer, Actos was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

66. Defendants failed to adequately warn Plaintiff Decedent and Plaintiff Decedent's prescribing physicians of human and animal results in preclinical studies pertaining to bladder cancer and Actos.

67. Defendants' failure to adequately warn Plaintiff Decedent and Plaintiff Decedent's prescribing physicians of a bladder cancer risk prevented Plaintiff Decedent's prescribing physicians and Plaintiff Decedent from correctly and fully evaluating the risks and benefits of Actos and pioglitazone hydrochloride.

68. Had Plaintiff Decedent been adequately warned of the potential life-threatening side effects of Defendants' Actos and pioglitazone hydrochloride, Plaintiff Decedent would not have purchased or taken Actos and could have chosen to request other treatments or prescription medications.

69. Upon information and belief, had Plaintiff Decedent's prescribing physicians been adequately warned of the potential life-threatening side effects of Defendants' Actos and pioglitazone hydrochloride, Plaintiff Decedent's prescribing physicians would have discussed the risks of bladder cancer and death associated with Actos with Plaintiff Decedent and/or would not have prescribed it to Plaintiff Decedent.

70. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff Decedent was caused to suffer from the aforementioned injuries and damages.

71. By reason of the foregoing, Plaintiff Decedent demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

THIRD CAUSE OF ACTION
AS AGAINST DEFENDANTS
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

72. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint

with the same force and effect as if more fully set forth herein.

73. Actos was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

74. At all times relevant, Actos was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff Decedent.

75. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Actos.

76. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation, because when it left the hands of Defendants' manufacturers and suppliers it was unreasonably dangerous and was also more dangerous than the ordinary consumer would expect.

77. At all times herein mentioned, Actos and pioglitazone hydrochloride was in a defective condition and was unsafe, and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when Actos was used in a form and manner instructed and provided by Defendants.

78. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common, intended use.

79. At the time of Plaintiff Decedent's use of Actos, it was being used for its intended purpose, and in a manner normally intended, namely for the treatment of Type 2 Diabetes Mellitus.

80. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that caused an unreasonable risk to the health of consumers, and to Plaintiff Decedent in particular, and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiff.

81. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Actos. This was demonstrated by the existence of other Type 2 Diabetes Mellitus medications which had a more established safety profile and a considerably lower risk profile.

82. Plaintiff Decedent could not, by the reasonable exercise of care, have discovered Actos' defects and perceived its danger.

83. The defects in Defendants' product were substantial and contributing factors in causing Plaintiff Decedent's injuries.

84. As a foreseeable, direct, legal, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff Decedent was caused to suffer from the aforementioned injuries and damages.

85. Due to the unreasonably dangerous condition of Actos, Defendants are strictly liable to Plaintiff Decedent.

86. By reason of the foregoing, Plaintiff Decedent demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of

\$75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

FOURTH CAUSE OF ACTION
AS AGAINST DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

87. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

88. Defendants expressly warranted that Actos was safe for its intended use and as otherwise described in this complaint. Actos did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient and animal studies, the representation that it was safe, and the representation that it did not have high and/or unacceptable levels of life-threatening side effects like bladder cancer, that it would improve health, maintain health, and potentially prolong life.

89. The express warranties represented by Defendants were a part of the basis for Plaintiff Decedent's use of Actos and Plaintiff Decedent relied on these warranties in deciding to use Actos.

90. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Actos and pioglitazone hydrochloride was to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

91. Actos does not conform to these express representations because Actos is not safe or effective and may produce serious side effects, including among other things bladder cancer, degrading Plaintiff Decedent's health, and shrinking their life expectancy resulting finally in death.

92. As a result of the foregoing breach of express warranty, Plaintiff Decedent was caused to

suffer bladder cancer and death, as well as other severe and personal injuries, which were permanent and lasting in nature including metastatic cancer, physical pain and mental anguish, including diminished enjoyment of life, as well as surgical procedures, medical treatment, monitoring and/or medications.

93. By reason of the foregoing, Plaintiff Decedent was severely and permanently injured, and required constant and continuous medical monitoring and treatment after his use of Defendants' Actos drug.

94. As a result of the foregoing acts and omissions, Plaintiff Decedent required more health care and services and did incur medical, health, incidental and related expenses.

95. By reason of the foregoing, Plaintiff Decedent demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

FIFTH CAUSE OF ACTION
AS AGAINST DEFENDANTS
(BREACH OF IMPLIED WARRANTY
FOR A PARTICULAR PURPOSE)

96. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

97. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

98. Defendants impliedly represented and warranted to the users of Actos that Actos was safe and fit for the particular purpose for which said product was to be used, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

99. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff Decedent's health and shortened their life expectancy.

100. Plaintiff Decedent relied on the implied warranty of fitness for a particular use and purpose.

101. Plaintiff Decedent reasonably relied upon the skill and judgment of Defendants as to whether Actos was safe and fit for its intended use.

102. Actos and pioglitazone hydrochloride were injected into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

103. Defendants breached the aforesaid implied warranty, as their drug Actos was not fit for its intended purposes and uses.

104. As a result of the foregoing breach of warranty, Plaintiff Decedent was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which were permanent and lasting in nature, including metastatic cancer, physical pain and mental anguish, including diminished enjoyment of life, as well as surgical procedures, medical treatment, monitoring and/or medications, and finally, death.

105. As a result of the foregoing acts and omissions Plaintiff Decedent required more health care and services and did incur medical, health, incidental and related expenses.

106. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and

further relief as the Court deems proper.

SIXTH CAUSE OF ACTION AS
AGAINST DEFENDANTS
(BREACH OF IMPLIED WARRANTY
OF MERCHANTABILITY)

107. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

108. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

109. Defendants marketed, sold and distributed Actos and knew and promoted the use for which Actos was being used by Plaintiff Decedent and impliedly warranted to Plaintiff that Actos was of merchantable quality and fit for the ordinary purpose for which it was intended, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

110. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff Decedent's health and shortened his life expectancy.

111. Plaintiff Decedent reasonably relied on the skill, expertise and judgment of Defendants and its representations as to the fact that Actos was of merchantable quality.

112. The Actos and pioglitazone hydrochloride manufactured and supplied by Defendants was not of merchantable quality, as warranted by Defendants in that the drug had dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

113. As a direct and proximate result of the foregoing, Plaintiff Decedent was caused bodily injury, pain and suffering and economic loss.

114. As a result of the foregoing acts and omissions, Plaintiff Decedent was caused to suffer

serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, including metastatic cancer, physical pain and mental anguish, including diminished enjoyment of life, as well as surgical procedures, medical treatment, monitoring and/or medications, and finally, death.

115. As a result of the foregoing acts and omissions Plaintiff Decedent required more health care and services and did incur medical, health, incidental and related expenses.

116. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

117. By reason of the foregoing, Plaintiff is entitled to compensatory and punitive damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

SEVENTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(LOSS OF CONSORTIUM)

118. Plaintiff incorporates by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

119. Plaintiff is entitled to the comfort, enjoyment, society and services of one another.

120. As a direct and proximate result of the foregoing, Plaintiff was deprived of the comfort and enjoyment of the services and society of Plaintiff Decedent and has suffered and will continue to suffer economic loss, and have otherwise been emotionally and economically injured. The Plaintiff's injuries and damages are permanent and continuing into the future. The Plaintiff seeks compensatory and punitive damages from the Defendant as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for all of Decedents' injuries in and amount to be determined at trial, as alleged herein;
2. Awarding pre-judgment and post-judgment interest to Plaintiff.
3. Awarding punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
4. Awarding Plaintiff's attorney's fees;
4. Awarding Plaintiff the costs of these proceedings; and
5. Granting all such other and further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: August 1, 2014.

By: s/ Neil D. Overholtz
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